

## **REMARKS**

### **I. Amendments**

#### **Drawings**

The drawings are objected to under 37 C.F.R. § 1.83(a) because they allegedly fail to show elements described in the specification.

Figure 9 is objected to as allegedly failing to show a loading means "12" and a sample "14" as described in the specification on page 9, line 10. Accordingly, in response to the Examiner's objection, the recitation of figure elements 12 and 14 has been deleted from page 9, line 10, of the specification. For the record, exemplary embodiments of loading means which can be used in the present invention are discussed on page 7, line 24- page 8, line 6, and illustrated in Figures 5, 9, and 10. Therefore, this feature of the invention is adequately described in the specification and shown in the drawings.

Figure 10 is objected to as allegedly failing to show the pre-alignment means "13" as described in the specification on page 9, line 14. Figure 10 has been amended to show the pre-alignment means as figure element 13.

Withdrawal of the objection to the drawings under 37 C.F.R. § 1.83(a) is respectfully requested.

#### **Specification**

The specification is objected to in view of the informalities or typographical errors listed on page 3 of the Office Action. The specification has been amended to correct these minor typographical errors in accordance with the Examiner's instructions. Accordingly, withdrawal of the objection is requested.

#### **Claims**

Claims 1 and 18 have been amended to incorporate the embodiments of original claims 4 and 5, now canceled.

Claim 19 is objected to for a minor informality. The Examiner requires that figure reference numeral "16" be deleted from the claim since there are no other reference numerals in

the claims. Claim 19 has been amended in accordance with the Examiner's requirement and, therefore withdrawal of the objection is requested.

No new matter has been added by any of the amendments herein.

## **II. The claimed invention**

The claimed invention is directed to an apparatus for presenting samples during spectroscopic analysis. The apparatus comprises means for feeding one or more samples sequentially and automatically through an analyzing position, and means for temporarily fixing the sample in the analyzing position. The means for fixing the sample comprises first and second holding parts having respective apertures. When in the closed position, the first and second apertures together define an effective optical aperture. Advantageously, no manual handling of the sample is required with the claimed invention. Furthermore, the claimed invention improves the precision of data obtained compared to prior art methods, and is especially suitable for spectroscopic analysis of pharmaceutical dosage forms, such as tablets and capsules.

## **III. Rejection under 35 U.S.C. § 102(b)**

Claims 1, 3-7, 10, and 11 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP 896,215 to Hammond et al. ("Hammond").

Anticipation requires that each and every feature of the claimed invention be disclosed in a single prior art document. Applicants submit that the claimed invention is not disclosed, either explicitly or inherently, by Hammond.

### **A. Hammond does not disclose means for feeding samples sequentially through at least one predetermined analysis position.**

Hammond discloses a method and apparatus for spectrometrically analyzing a tablet by near infrared analysis. A tablet 20 is clamped in a sample holder 1 having a recess 5. The tablet is clamped in the recess 5 using spring-loaded rods 8 and 12 to maintain the tablet in a predetermined position. (See Abstract) Hammond discloses that the sample is provided to the analysis apparatus manually, and provides that:

“it is preferred that the recess within which the tablet is accommodated is provided in a tablet holder which is readily removable from and inserted into the spectrophotometer for convenience of changing tablets.” (col. 7, lines 16-20)

The rods 8 and 12 which project into the recess 5 are used to clamp and maintain the tablet in position during analysis (col. 8, lines 56-58; and col. 9, lines 6-11). Hammond discloses that rods 8 and 12 are provided with levers 11 and 15, respectively, which are used for “manually displacing the rod[s] 8 [and 12] against its spring loading to withdraw the rod from the recess” (col. 9, lines 3-6 and 13-15). In accordance with Hammond, therefore, the sample holder must be manually manipulated in order to position, and later remove, the sample from the holder. As such, Hammond only discloses a manual operation by which a tablet sample is placed in a sample holder and then removed, which manual procedure is then repeated with each sample. Accordingly, the apparatus and method of Hammond does not allow for an automated analyzing procedure for use at-line or on-line in a manufacturing process.

In contrast, the claimed invention obviates the requirement for manual insertion or manipulation of the sample in the sample holder. Therefore, the claimed invention defines an apparatus and method for an automated procedure which, advantageously, can be used at-line or on-line in a manufacturing process. Specifically, as disclosed in the specification, the claimed invention provides:

“...an automated and continuous analysis of samples on-line... In contrast to prior art techniques the present invention provides an apparatus for fast and reliable measurements in which there is no need for manual handling of the samples”. (page 4, lines 26-30)

*Just one* For example, the claimed invention as defined by claim 1 is characterized by *means for feeding one or more samples sequentially*, i.e., consecutively and automatically, through at least one predetermined analyzing position. One example of such means for sequentially feeding the sample is illustrated in Fig. 3. Thus, the need for manual insertion and replacement of samples is obviated.

This feature of the present invention, which provides for sequential feeding of samples to the analyzing device, is not disclosed by Hammond. Absent manual presentation, Hammond does not disclose a means for presenting samples sequentially and continuously to the spectrophotometer.

**B. Hammond does not disclose a means for fixing the sample in an analyzing position, which comprises a first holding part defining a first aperture, and a second holding part defining a second aperture.**

As discussed in Section A above, Hammond discloses that the sample 20 to be analyzed is placed in the sample holder 1, and is:

“subjected to clamping forces applied by two spring loaded clamping rods disposed substantially perpendicularly relative to each other in the tablet holder. The effect of clamping the tablet in the table holder permits reproducible analysis measurements to be achieved...” (Abstract)

Hammond discloses that the tablet holding parts are the two spring-loaded clamping rods 8 and 12 which maintain the tablet in a fixed position. These rods 8 and 12 are not described as having passageways for transmittal of radiation and, therefore, the rods are solid components of the prior art apparatus (Figures 1-3 and 6) which cannot permit a beam of radiation to pass through to the sample.

In contrast, the sample holding means of the claimed invention is distinguished over Hammond by the presence of first and second holding parts in which are defined respective first and second apertures. The first and second apertures together define the beam path for radiation to and through the sample (page 11, lines 4-11). The radiation enters the first aperture, proceeds through the sample, and then exits through the second aperture (Fig. 7; and page 6, lines 13-14).

Hammond's device is not structurally configured with two sample holding parts, each of which contains an aperture for permitting a sample beam to pass. This feature of the present invention is not disclosed by Hammond.

**C. Hammond does not disclose first and second apertures which together define a beam path and an effective optical aperture in the closed position.**

Hammond discloses that the tablet holder has only a single aperture 7 through which the radiation is transmitted. The tablet holder has an open top facing the sample beam, and the tablet rests on top of aperture 7 (Fig. 2; and page 9, lines 30-47). The effective optical aperture is defined by this single aperture 7. As shown in Figures 2 and 4, after radiation exits the source, it

passes through the tablet and the single aperture 7, and is detected by the detector. There is no other structure in Hammond defining the effective optical aperture other than element 7.

The claimed invention is distinguished over Hammond by the presence of two apertures in the two sample holding parts surrounding the sample (page 11, lines 4-10). When the two sample holding parts (for example, elements 9a and 9b in Figures 5 and 6) are joined together and enclose the sample, they define the beam path and effective optical aperture through which radiation is transmitted from the source, through the sample, to the detector. This effective optical aperture is formed by the cooperation of the first and second apertures in the sample holding parts.

Such a structure, in which the effective optical aperture is defined by the cooperation of the first and second sample holding parts in the closed position, is not disclosed by Hammond.

In summary, therefore, the claimed invention is distinguished over Hammond by at least the three features discussed above. In brief, Hammond does not disclose, either inherently or explicitly, the following features of the claimed invention:

1. means for automatically feeding samples sequentially through at least one predetermined analysis position;
2. means for fixing the sample in an analyzing position, which comprises a first holding part defining a first aperture, and a second holding part defining a second aperture; and
3. the first and second apertures together define an effective beam pathway in the closed position.

Therefore, Hammond fails as an anticipatory reference and the claimed invention is novel. Accordingly, the rejection of claims 1, 3-7, 10, and 11 under §102(b) is improper and should be withdrawn.

#### **IV Rejection under 35 U.S.C. § 103(a)**

Claims 2, 8, 9, 12-23, 25, and 26 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hammond in view of DE 44 41 686 to Schilling ("Schilling"). The Examiner alleges that it would have been obvious to combine Hammond with Schilling to obtain the claimed invention.

Applicants submit that their comments in Section III above, regarding the rejection under 35 U.S.C. § 102(b) in view of Hammond, is applicable and therefore responsive to the rejection under § 103(a). In brief, the claimed invention is not anticipated by Hammond. Schilling does not overcome the deficiencies of Hammond to suggest the claimed invention.

Furthermore, independent claims 1 and 18 were amended to incorporate the embodiments of claims 4 and 5 which were not rejected under §103(a). Accordingly, claims 2, 8, 9, 12-23, 25, and 26, which are dependent either directly or indirectly on amended claim 1 or 18, are patentable over the cited combination of Hammond and Schilling for the same reasons that claims 4 and 5 were deemed to be not obvious over the cited combination of references.

Therefore, withdrawal of the rejection of the claims under 35 U.S.C. § 103(a) is respectfully requested.

The following documents have been made of record but not relied up for a prior art rejection: US 4,319,269; US 4,472,960; US 6,275,294; and US 6,244,118. Applicants submit that the cited documents neither disclose nor suggest the claimed invention.

It has come to Applicants' attention that the Information Disclosure Statement ("IDS") filed July 10, 2002 was never entered into the application file. Accordingly, Applicants are providing a duplicate copy of the previously-filed IDS and references cited therein, as well as a copy of the return postcard confirming receipt of the IDS and references by the PTO.

## V. Conclusion

Upon entry of this Amendment, claims 1-3, 6-23, 25, and 26 are pending. Applicants respectfully submit that claims 1-3, 6-23, 25, and 26 have been distinguished over the cited prior art, and are directed to patentable subject matter. Accordingly, Applicants request allowance of the claims.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

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Respectfully submitted,

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